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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,884	08/21/2003	Leonid A. Rozov	ANA-5942	8189

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EXAMINER

KEYS, ROSALYND ANN

ART UNIT PAPER NUMBER

1621

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/645,884	ROZOV ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rosalynd Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/14/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-5 are pending.

Claims 1-5 are rejected.

### ***Information Disclosure Statement***

2. The information disclosure statement filed November 14, 2003 has been considered, except for FR 2577410. This reference was not considered because it fails to comply with 37 CFR 1.98(a)(3) which requires a concise explanation of the relevance of each reference, which is not in the English language, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of said references.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cicco (US 5,026,924).

The instant invention is directed to a method of preparing desflurane comprising reacting isoflurane with 0.7-1.2 mol.% of antimony pentachloride and 1.3-2.2 molar equivalents of hydrogen fluoride. The reaction temperature range is 9-18°C. The reaction is conducted for about 6 to 7 hours after the addition of hydrogen fluoride is completed. The hydrogen fluoride is added at a rate of 0.25 to 1.5 molar equivalents per hour.

Cicco teaches a method of preparing desflurane comprising reacting isoflurane with from about 1.0 to about 6.0 weight % of antimony pentachloride and a mole ratio of isoflurane to hydrogen fluoride of from about 1:0.1 to about 1:7, preferably from about 1:1 to about 1:4, and most preferably about 1:2 (see

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column 2, line 23 to column 3, line 12). The reaction temperature range is from about – 10°C to about 30°C, preferably in the range of from about 7°C to about 18°C (see column 2, lines 23-31 and column 3, line 3-8). The reaction is conducted for about 4 hours after the addition of hydrogen fluoride is completed (see Example 1). The rate of addition of hydrogen fluoride to reaction mixture is not critical and can vary widely. However, it is preferably added at a rate of about 0.01 to about 0.1 parts by weight per hour (see column 3, lines 37-42).

Cicco differ from the instant invention in that Cicco do specifically disclose the claimed antimony pentachloride and hydrofluoride amounts. However, the claimed amounts are clearly suggested by Cicco. It has been held that in the case where claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). Further, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

With respect to the differences in the amount of additional time the reaction is conducted after the addition of hydrogen fluoride. One having ordinary skill in the art would have found it obvious to carry out the reaction longer in order to increase the product yield.

***Analysis of Data for Showing of Unexpected Results***

7. The Examiner considered the comparative data given in the Examples of the specification. First, the Examiner did not consider the results to be unexpected because from the teaching of Cicco one having ordinary skill in the art would conclude that by that by varying the ratio of isoflurane to hydrogen fluoride one would vary the yield of desflurane and the conversion of isoflurane (see the Examples in U.S. Patent 5,026,924). Second, the Examiner did not consider the data to be sufficient to avoid a prima facie obviousness rejection because the comparison is not a side-by side comparison, i.e., the Applicants have made a comparison between the instant invention and Example 1 of US Patent No. 5,026,924 rather than comparing the amount of the antimony pentachloride and hydrogen fluoride present in Example 1 with the claimed amounts of antimony pentachloride and hydrogen fluoride under identical reaction conditions. Such a comparison would allow one of ordinary skill in the art to clearly see that it is the claimed concentration of the antimony pentachloride and hydrogen fluoride that produce unexpected results.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M and F 3:00-8:00 pm and T-R 5:30-10:30 am.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Rosalynd Keys  
Primary Examiner  
Art Unit 1621

March 20, 2004